(2) Bovine, caprine, and ovine cells shall, in addition, be tested for:
(i) Bluetongue virus;
(ii) Bovine adenoviruses;
(iii) Bovine parvovirus; and
(iv) Bovine respiratory syncytial virus.
(3) Canine cells shall, in addition, be tested for:
(i) Canine coronavirus;
(ii) Canine distemper virus; and
(iii) Canine parvovirus.
(4) Equine cells shall, in addition, be tested for:
(i) Equine herpesvirus; and
(ii) Equine viral arteritis virus.
(5) Feline cells shall, in addition, be tested for:
(i) Feline infectious peritonitis virus; and
(ii) Feline panleukopenia virus.
(6) Porcine cells shall, in addition, be tested for:
(i) Porcine adenovirus;
(ii) Porcine parvovirus;
(iii) transmissible gastroenteritis virus; and
(iv) Porcine hemagglutinating encephalitis virus.
(7) Firms that do not have rabies virus on premises either for research or production purposes are exempt from having to produce positive rabies virus control monolayers. Fixed positive rabies virus control monolayers will be provided by the National Veterinary Services Laboratories.
(c) After staining, each group of monolayers shall be examined for the presence of specific fluorescence attributable to the presence of extraneous viruses.
(1) If the material under test shows any evidence of specific viral fluorescence, it is unsatisfactory and may not be used; *Provided*, That, if specific fluorescence attributable to the virus being tested for is absent in the positive control monolayers, the test is inconclusive and may be repeated.
(2) If the fluorescence of the monolayers inoculated with the specific virus as positive controls is equivocal, or if the negative monolayers show equivocal fluorescence indicating possible viral contamination, or both, the test shall be declared inconclusive, and may be repeated; *Provided*, That, if the test is not repeated, the material under test shall be regarded as unsatisfactory for use in the production of biologics.

[60 FR 24548, May 9, 1995]

INGREDIENT REQUIREMENTS

§ 113.50 Ingredients of biological products.

All ingredients used in a licensed biological product shall meet accepted standards of purity and quality; shall be sufficiently nontoxic so that the amount present in the recommended dose of the product shall not be toxic to the recipient; and in the combinations used shall not denature the specific substances in the product below the minimum acceptable potency within the dating period when stored at the recommended temperature.

[38 FR 29889, Oct. 30, 1973]

§ 113.51 Requirements for primary cells used for production of biologics.

Primary cells used to prepare biological products shall be derived from normal tissue of healthy animals. When prescribed in an applicable Standard Requirement or in the filed Outline of Production, each batch of primary cells used to prepare a biological product shall be tested as prescribed in this section. A batch of primary cells found unsatisfactory by any prescribed test shall not be used. A serial of biological product shall not be released if produced from primary cells that are found unsatisfactory by any prescribed test.
(a) Final container samples of completed product or samples of the final pool of harvested material or samples of each subculture of cells used to prepare the biological product shall be shown free of mycoplasma as prescribed in § 113.28. The sample for testing shall consist of at least 75 cm^2 of actively growing cells or the equivalent in harvest fluids; *Provided*, That all sources of cells in the batch of primary cells are represented.
(b) Final container samples of completed product or samples of the final pool of harvested material or samples of each subculture of cells used to prepare the biological product shall be